Guidelines for OVHA Coverage

ITEM: HOME UTERINE ACTIVITY MONITOR

DEFINITON: A device that measures uterine contraction, worn by pregnant women who are at high risk for preterm birth, to provide early detection of preterm labor. Uterine activity is measured in the home, the data is transmitted to a clinical setting, and reviewed by clinical staff in that setting. It is generally used twice per day, for one hour.

GUIDELINES: There is a significant degree of controversy in the literature regarding the efficacy of home uterine monitoring, with or without frequent nursing contact, in the detection of preterm labor, the prevention of preterm birth, and neonatal morbidity.
Use of the home uterine activity monitor (HUAM) should therefore be given significant consideration.
The HUAM may be appropriate for the individual who:

- Is at least 24 weeks gestation (FDA) AND
- Who has a history of preterm labor, preterm birth (FDA), uterine anomalies, history of spontaneous abortions, or exposure to diethylstilbestrol (Regence BCBS) AND
- Whose physician is a VT Medicaid provider specializing in the area of high risk obstetrics AND is an active provider with VT Medicaid AND
- Who demonstrates the ability and motivation to follow through with the proper use of the HUAM AND
- Who has received training in its proper use and demonstrated that knowledge to a skilled practitioner.

The FDA requires that the following information be provided to each beneficiary with a HUAM device:
"This HUAM only monitors uterine activity and provides this information to the physician for assessment and, if necessary, intervention. This HUAM does not prevent the onset of preterm labor nor will it prevent the occurrence of preterm birth."
"Clinical studies have shown that when a patient at risk for preterm labor is already enrolled in a daily nursing contact program, the HUAM does not provide any added effectiveness, i.e., a higher rate of detection of preterm labor over and above the detection rate associated with the daily nursing contact."
"No widely accepted controlled studies have been conducted that show that this device is effective at the early detection of preterm labor other than in patients with a preterm delivery." (FDA)

APPLICABLE CODE:
S9001 Home uterine monitor with or without associated nursing services. Limit: 3 month rental. PA required.

CAUTIONS:
The "FDA has identified five risks to health associated with this type of device. These risks are: electrical shock and/or injury, skin irritation and sensitization (from abdominal belt or tocotransducer), unnecessary evaluation and treatment (from over-diagnosis), potential harmful

effects from treatment with tocolytics, use of unproven patient subpopulations (with shifted risk-benefit)." (FDA)

EXAMPLES OF DIAGNOSES: Past history of preterm labor and/or preterm birth, uterine anomalies, history of spontaneous abortions, history of exposure to diethylstilbestrol.

REQUIRED DOCUMENTATION:

- Current, complete Certificate of Medical Necessity form.
- Supporting documentation demonstrating that the beneficiary is at least 24 weeks gestation (FDA) AND who has a history of preterm labor, preterm birth (FDA), uterine anomalies, history of spontaneous abortions, or exposure to diethylstilbestrol (Regence BCBS) AND whose physician is a VT Medicaid provider specializing in the area of high risk obstetrics AND is an active provider with VT Medicaid AND who demonstrates the ability and motivation to follow through with the proper use of the HUAM AND who has received training in its proper use and demonstrated that knowledge to a skilled practitioner.
- Supporting documentation demonstrating that the beneficiary has received the following information as required by the FDA:

"This HUAM only monitors uterine activity and provides this information to the physician for assessment and, if necessary, intervention. This HUAM does not prevent the onset of preterm labor nor will it prevent the occurrence of preterm birth."
"Clinical studies have shown that when a patient at risk for preterm labor is already enrolled in a daily nursing contact program, the HUAM does not provide any added effectiveness, i.e., a higher rate of detection of preterm labor over and above the detection rate associated with the daily nursing contact."
"No widely accepted controlled studies have been conducted that show that this device is effective at the early detection of preterm labor other than in patients with a preterm delivery." (FDA)

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Treatments, tests, and technologies to delay or prevent preterm birth. www.sidelines.org.

Complications, including preterm labor. Matria Co. www.gynob.com.

Medical Policy Manual: Topic: Home uterine activity monitoring. The Regence Group (Blue Cross/Blue Shield). www.regence.com.

Medical Director's signature:_____

OVHA Director's signature:_____

Date:
Revision 1:
Revision 2: